

III. REMARKS

1. In the Office Action of March 1, 2004, claims 13-35 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In this respect, the Office Action of March 1, 2004 indicates that the written description does not disclose a neuro-efficiency parameter being derived from an inspiratory effort signal, but instead stipulates that it is derived from diaphragm EMGdi signal intensity correlated to lung volume. We presume that the expression "neuro-efficiency parameter" used by the Examiner refers to the expression "neuro-ventilatory efficiency parameter" used in the claims.

This objection is respectfully traversed for the following reasons.

The specification of the present patent application, page 2, lines 5-7 indicates that "[n]euro-ventilatory is a form used to express the amount of neural drive (breathing effort) needed to obtain a given tidal lung volume" [emphasis added]. Therefore, it is clear from the disclosure of the present patent application that "neuro-ventilatory efficiency parameter" is in direct relation to the breathing effort of a patient.

Furthermore, the specification of the present patent application, page 18, lines 6-8 indicates that "[t] neuro-ventilatory efficiency is obtained by relating the diaphragm EMGdi signal intensity to changes in lung volumes, or by relating the lung volume to changes in diaphragm EMGdi signal intensity". It is understood that breathing effort is directly related to the flexing of the diaphragm, the measurement of which corresponds to an EMGdi signal intensity (see for instance page 4, lines 15-17:

"In the present invention, the use of crural diaphragm EMG rests on the assumption that neural drive to the crural diaphragm is representative for the total respiratory drive".) It is therefore clear that the disclosure of the present application correlates neuro-ventilatory efficiency to breathing effort (or inspiratory effort).

Claims 13, 18, 21, 23, 24, 30, 33 and 35 were amended to replace the expression "inspiratory effort" with "breathing effort". Claims 24 and 25 were amended to response to Examiner's comments regarding the use of the word "control".

In the Office Action of March 28, 2003, claims 13 and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Younes (U.S. Patent No. 5,107,830). Claims 20 and 32 are also rejected as being unpatentable over Younes in view of Ernst (U.S. Patent No. 3,961,627). Claims 23 and 35 are also rejected as being unpatentable over Younes in view of Sackner (U.S. Patent No. 6,015,388).

More specifically, the Examiner indicates that, in regards to claim 24, Younes discloses a ventilatory having:

- a first input (P_{oub} μuo) for receiving a first signal representative of inspiratory effort and which would have an amplitude;
- a second input (Volume feed back see figs 7 and 9 and supporting text) for receiving a second signal representative of volume and which would have a second amplitude;

a calculator which is fully capable of calculating a relationship between the first and second signals (pre-programmed electronics 22), and that is fully capable of calculating the ratio in a manner that falls within the ambit of neuro-ventilatory efficiency; and

a control dependant on whether a present calculated value of said "neuro-ventilatory efficiency" is higher or lower than a past calculation of the "neuro-ventilatory efficiency" by an amount exceeding a given threshold (pre-programmed electronics 22) to then increase or decrease the ventilatory assist level.

The Applicant respectfully disagrees. Younes simply does not disclose nor render obvious the calculation of a neuro-ventilatory efficiency representative parameter that constitutes a limitation of the claimed invention. Neither does Younes disclose or render obvious increasing or decreasing the ventilatory assist level depending on whether a present calculated value of the neuro-ventilatory efficiency representative parameter is higher or lower than a past calculated value of said neuro-ventilatory efficiency representative parameter by an amount exceeding a given threshold.

In the respiratory art, "neuro-ventilatory efficiency" is a term used to express the amount of neural drive needed to obtain a given tidal lung volume, it is not a concept that can be broadly interpreted as does the Examiner in his arguments. In the claimed invention, the pressure assist unit provides a pressure, flow, or volume assist that is adjusted in proportion to changes in the neuro-ventilatory efficiency (e.g. the EMGdi signal intensity) at a given lung volume or vice versa. The pressure,

flow, or volume assist unit continuously operate to maintain a tracheal pressure, flow or volume that is adjusted in proportion to changes in neuro-ventilatory efficiency.

In Younes, the disclosure is limited to providing a ventilation unit and ventilating procedure that are able to deliver air to a patient in proportion to patient ongoing inspiratory effort. In other words, the machine generated pressure as disclosed in Younes is a function of pressure generated by respiratory muscles only (i.e., P_{mus} - see for instance the equation at column 10, line 18), not breathing effort and lung volume as in the claimed invention. Therefore, the claimed invention has the advantage over the apparatus and method disclosed in Younes of being capable of providing increased ventilatory assist in case of weakened respiratory function, which function is absent from Younes.

The Examiner argues that the pre-programmed electronics 22 of Younes is capable of calculating a neuro-ventilatory efficiency representative parameter. Even if we suppose that the pre-programmed electronics 22 of Younes could be programmed to calculate a neuro-ventilatory efficiency representative parameter, neither Younes nor the other cited prior art indicate how or why it would be useful to do so. As such, the claimed invention as described in independent claims 13 and 24 is clearly not rendered obvious by Younes as argued by the Examiner.

For a more thorough analysis of the disclosure of Younes, the Applicant refers the Examiner to the Office Action response dated September 25, 2003.

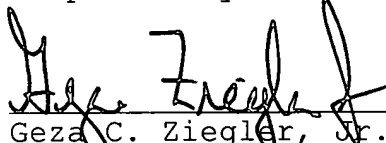
The remaining pending claims are all dependant upon either claim 13 or 24 and are thus believed to also be patentable over the prior art cited.

In light of the submission made herein, Applicant believes that the present patent application is in condition for allowance and an early notice to that effect is respectfully solicited.

For all of the foregoing reasons, it is respectfully submitted that all of the claims now present in the application are clearly novel and patentable over the prior art of record, and are in proper form for allowance. Accordingly, favorable reconsideration and allowance is respectfully requested. Should any unresolved issues remain, the Examiner is invited to call Applicants' attorney at the telephone number indicated below.

A check in the amount of \$950 is enclosed for a three-month extension of time. The Commissioner is hereby authorized to charge payment for any fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,



Geza C. Ziegler, Jr.
Reg. No. 44,004

18 August 2004
Date

Perman & Green, LLP
425 Post Road
Fairfield, CT 06824
(203) 259-1800 Ext. 134
Customer No.: 2512

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date indicated below as first class mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 8/18/04

Signature: Doris W. Reiman
Person Making Deposit